MODELING THE MORTALITY IMPACT OF BUDGET THRESHOLDS

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Objectives

- One proposed approach to limiting spending on health care is to use budget impact analyses to assess the costs of new therapies and set spending limits.
- While there are various methods to address short-term affordability, the Institute for Clinical and Economic Review (ICER) does so by setting a budget threshold for all new market entrants.
- We explored the impact of an affordability threshold on patient outcomes by calculating ICER's proposed budget thresholds and modeling how restrictions based on such thresholds would have limited access to atorvastatin (Lipitor).
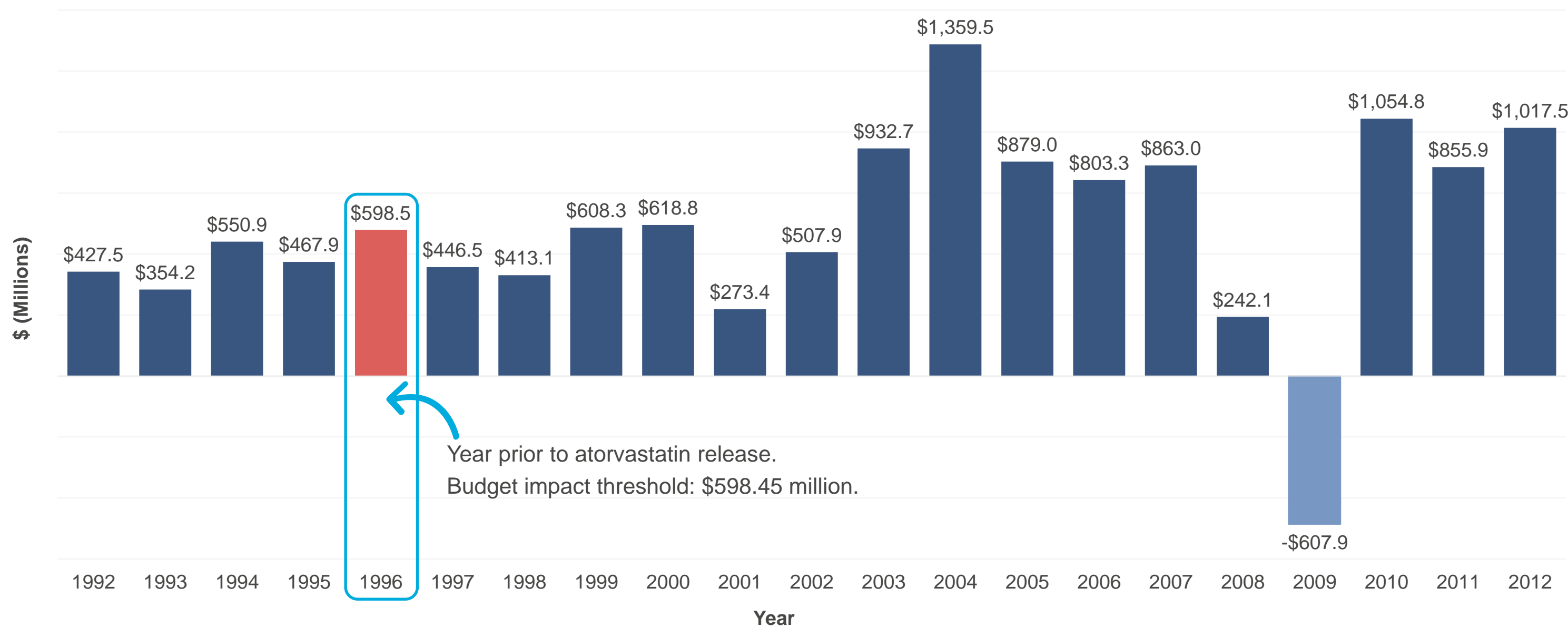
Methods

- We utilized ICER's methodology to calculate short-term budget thresholds from 1992 to 2012 using data including GDP, GDP growth, health expenditures, and number of new drugs approved in the previous two years.
- The implications when implementing such a threshold were explored using atorvastatin as an example, specifically:
  - The number of patients who would receive atorvastatin given the threshold was identified;
  - The clinical impact to those who would have been denied atorvastatin was estimated.
- Atorvastatin was compared to a market basket of treatments that was reflective of care for high cholesterol prior to its release, including other statins, gemfibrozil, and niacin.[1-7]
- We assumed once spending on atorvastatin reached the calculated budget threshold of the year prior to launch, the remaining patient population resorted to treatment patterns prior to atorvastatin launch.
- Historical utilization and health outcomes were compared with this counterfactual scenario where access to atorvastatin was limited.[8]

Results

- When using the ICER methodology, the budget impact threshold for each new therapy would have been $598 million (USD) in 1996, and varied considerably between years (**Figure 1**).[9-11]

FIGURE 1: BUDGET IMPACT THRESHOLD ($ MILLIONS), 1992 - 2012

Year prior to atorvastatin release.
Budget impact threshold: $598.45 million.

- In 1997, 2.9 million people received atorvastatin at a total cost of $2.96 billion.
- If an explicit budget threshold based on ICER's methodology had been imposed at atorvastatin's launch, only 28% (818,616) of the 2.9 million actual atorvastatin users would have received treatment (**Figure 2**).
- With the remaining 72% of patients forced to receive the less clinically effective previous standard of care under the ICER methodology, there would have been an additional 18,771 deaths due to complications of hyperlipidemia (**Figure 3**).[12,13]

FIGURE 2: ATORVASTATIN UTILIZATION WHEN APPLYING A BUDGET IMPACT THRESHOLD

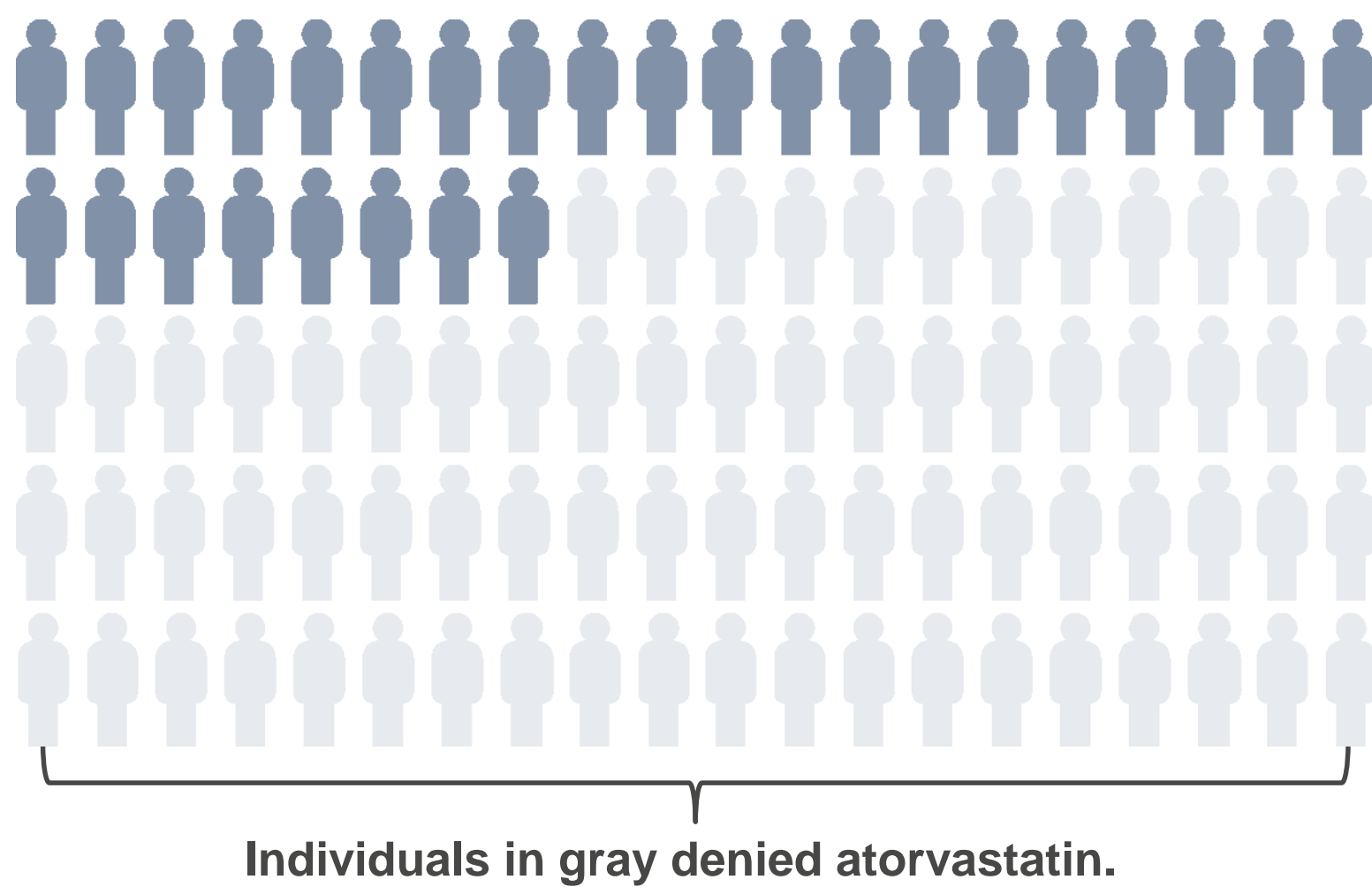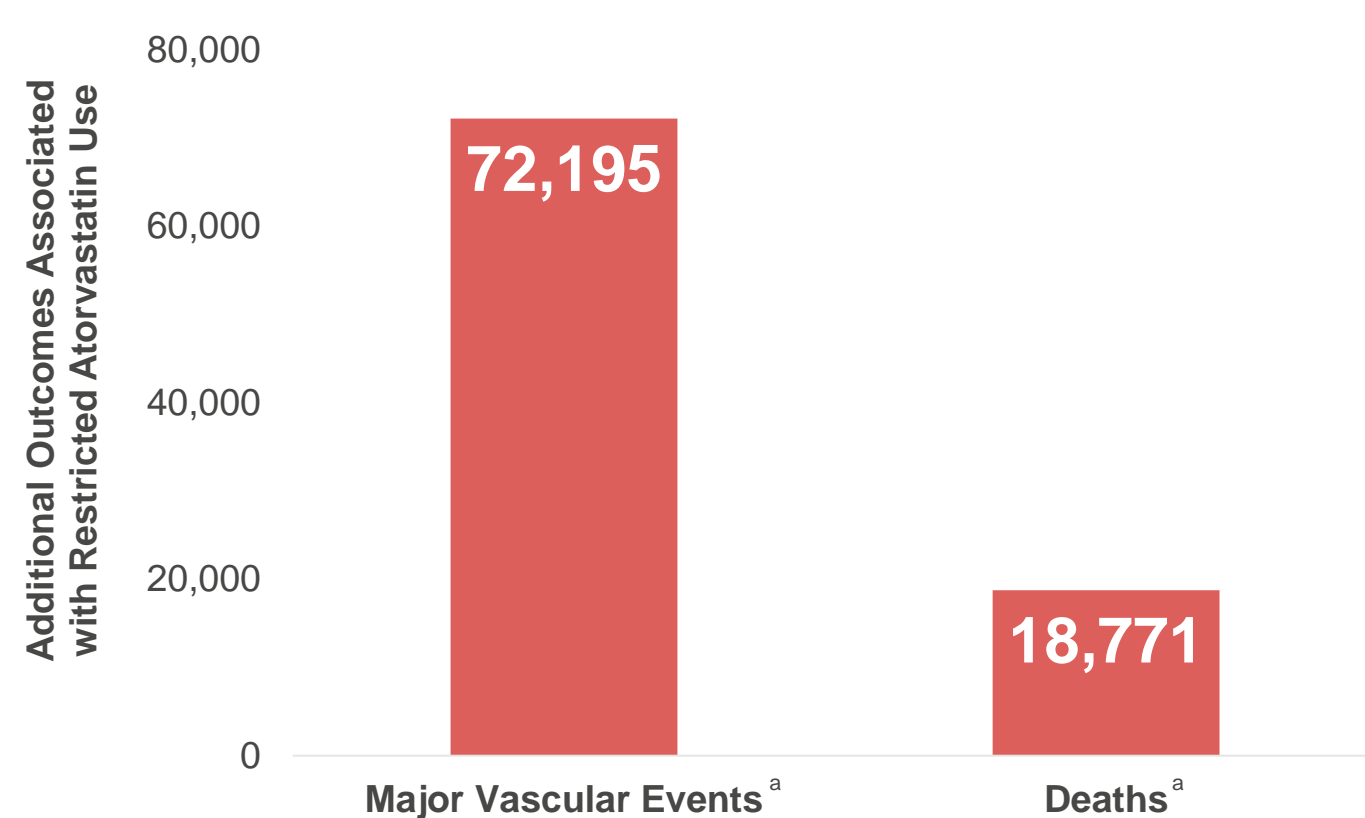**Individuals in gray denied atorvastatin.**

FIGURE 3: HYPOTHETICAL CLINICAL IMPACT OF LIMITING STATIN USE BASED ON ICER'S BUDGET IMPACT THRESHOLD

[a] Assumed relative risk (RR) of event per 1 mmol/L decrease in cholesterol of 0.76, RR of death of 0.91. Assumed 5 years of cholesterol reduction with treatment, baseline cholesterol level of 240.[8]

Conclusions

- Using metrics with substantial year-over-year variability leads to the estimation of highly variable budget thresholds (range of $0 to $1.36 billion per drug from 1992 to 2012) and makes pricing limits dependent on when a drug is approved.
- Implementing a single budget threshold across disease areas could deprioritize coverage of treatments for conditions with high clinical burden and large populations, even when treatments are clinically beneficial and deemed cost effective.
- In the case of atorvastatin, limiting utilization based on a budget threshold would likely have increased hyperlipidemia-related deaths.

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